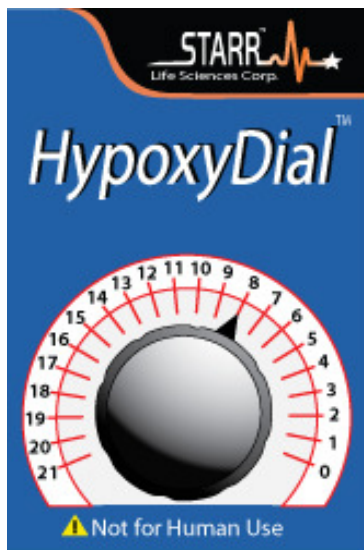




*HypoxyDial*TM

Patents Pending

User Manual

**STARR Life Sciences Corp.
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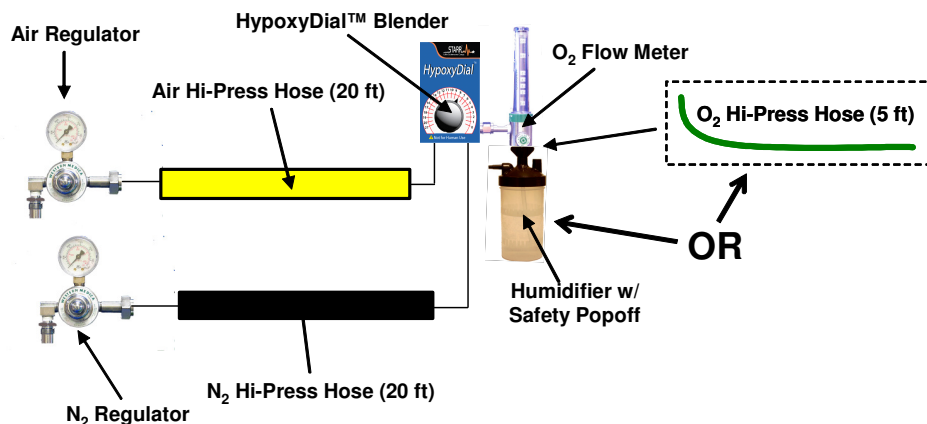
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1. Introduction and General System Layout

Thank you for purchasing the HypoxyDial™ from STARR Life Sciences®. The HypoxyDial™ is the simplest device available that will allow you to quickly and easily adjust fractional oxygen delivered to your animals. We hope that you will be completely satisfied with the system.

A basic schematic of the HypoxyDial™ system is given below.



2. HypoxyDial™ Packaged Parts

The following is a list of parts that should be included in your HypoxyDial™ shipping box:

- HypoxyDial™ Blender
- Nitrogen Pressure Regulator (50 psig preset, CGA 580 inlet fitting)
- Medical Grade Air Pressure Regulator (50 psig preset, CGA 346 inlet fitting)
- Nitrogen Supply Hose (20 ft, black)
- Air Supply Hose (20 ft, yellow)
- Flowmeter (Rotameter)
- Humidifier Chamber with Pressure Safety Popoff
- High-Pressure Outlet Hose (5 ft, green)
- Tripod Stand with Blender Mount
- HypoxyDial™ User Manual

Please check to see that you have all of these parts. If you find any part missing, please contact STARR Life Sciences at 1-866-9STARR9 ext. 9, or by e-mail at support@starrlifesciences.com.

3. System Requirements and Detailed Description

3.1. Basic HypoxyDial™ System Specifications

Product Description:

The HypoxyDial™ System is a product that allows you to quickly and easily dial any oxygen fraction ($F_{I}O_2$) in Air/ N_2 gas mixtures between 0 and 21%. Using universal fittings, the system connects to centralized

supplies (bottles or wall outlets) of air and nitrogen. The user simply turns a dial to set the oxygen percentage, and can adjust the outlet flow rate to obtain a constant stream of gas at the desired $F_{I}O_2$ and flow rate. The system is purely mechanical and uses no electrical power. All hoses and fittings to connect from the bottled gas source to the HypoxyDial™ system are provided.

$F_{I}O_2$ Range:

0 to 21%

Outlet Flow Rate Range:

0 to 15 L/min [Air/N₂]

Note: You can open the flow valve beyond the indicated maximum flow of 15 L/min to provide an actual maximum flush flow of ~30 L/min.

Bottle/Tank Input Gases:

Air (Medical-Grade) with Standard CGA 346 Fitting

Nitrogen with Standard CGA 580 Fitting

System Input Gas Pressure:

Up to 1500 psi (10.3 MPa) with gas tanks

OR

50 ± 10 psi (345 ± 70 kPa) to blender

USE ONLY THE PARTS THAT COME WITH YOUR HypoxyDial™ SYSTEM !! DO NOT SUBSTITUTE ANY PARTS !!

3.2. HypoxyDial™ Regulators

The pressure regulators that are provided with your HypoxyDial™, and that attach to the supply gas sources, are preset to 50 psig. **DO NOT tamper with these regulators as the presetting allows your system to operate safely and accurately.** The regulators do not need any specific maintenance, although we recommend that you use clean gas sources that do not contain rust, water or other particulate matter.

3.3. HypoxyDial™ Gas Blender

The gas blender is the heart of the HypoxyDial™. Although it is a purely passive, mechanical device, it is important that you understand its basic operation and maintenance requirements. Important details regarding these issues are provided below.

Gas Mixture Accuracy

If there is sufficient flow through the blender (see details in Outlet Delivery Ports section below), the blender will be accurate to ±1% $F_{I}O_2$. To assure accuracy, some other considerations are germane:

- If better accuracy is desired, we recommend that you compare the $F_{I}O_2$ at your dial setting with that from an oxygen analyzer.
- Use only clean, dry, medical-grade supply gases.
- Always allow sufficient time for equilibration of the gas mixture at your downstream delivery point after adjusting the $F_{I}O_2$. The equilibration time is dependent on the volume of tubing/hose and other parts connected to the blender.

Inlet/Supply Gas Pressure

The air and nitrogen inlet/supply pressures must be 50 psig in order for the flow meter to work properly. The regulators that come with your HypoxyDial™ system are preset to 50 psig outlet pressure. DO NOT tamper with these regulators.

Supply Gas Pressure Differential – Reed Alarm

The blender is equipped with a passive alarm (reed alarm) that will indicate when the gas supply pressures differ. The alarm, which has the sound of a loud whistle, will activate whenever the two inlet gas pressures differ by more than 15 - 20 psig. The alarm can sound for a number of reasons:

- *Startup* - If the gas supplies are not simultaneously pressurized, or if only one gas supply source is pressurized
- *Shutdown* - If the gas supply pressures bleed down at different rates when they are turned off, or if only one of the supplies was closed
- *Depleted Gas* - One of the supply gas sources is depleting, causing its pressure to drop
- *Regulator Tampering* - If someone has tampered with the regulators so that they are not set at 50 psig

Outlet Delivery Ports

The blender has 2 outlet delivery ports labeled “Outlet no bleed Accurate 3-30 LPM” (left side) and “Outlet w/bleed Accurate 0-30 LPM” (right side). Both ports deliver the same blended gas, but they differ slightly in function. This is because the blender dial face is only accurate if there is sufficient flow passing through the blender. One port automatically bleeds a sufficient bypass flow to achieve this accuracy (the “bleed” port), while the other requires you to select flows above a minimum flow to obtain accurate mixtures (the “no bleed” port). **The “bleed” port will automatically vent 2.5 to 3.5 L/min of blended gas continuously out of the bottom of the blender whenever you connect a device to that port and your gas supplies are pressurized.** Detailed descriptions of each are provided here.

Left Side – No Bleed

Minimum Required User-Selected Flow - 3 L/min

Gas Vented – none

Notes: All gas leaves the blender through this port, so there is no bypass flow.

Right Side – w/Bleed

Minimum Required User-Selected Flow - 0 L/min

Gas Vented – up to 3.5 L/min continuously

Notes: You must shut off your gas supplies when not using the system AND you have the flowmeter connected to this port. There is a check valve that opens the bypass flow to be activated when you connect to the fitting on this port.

Other Notes

- DO NOT tape over or block any of the ports on the bottom of the blender.
- DO NOT immerse the blender in any liquids.
- DO NOT steam clean or autoclave the blender.
- Clean blender surfaces using a 10% bleach solution or light detergent in water.

Blender Maintenance

The blender functions using various elastomeric components such as seals and O-rings. These materials will degrade and/or wear over time, commensurate with the level of usage and cleanliness of the supply gases, resulting in degradation of performance (reduction in accuracy). These materials are designed

to function for a minimum of 2 years, but will eventually need to be replaced. A service life of 3 years should be considered maximum, even under the best conditions.

To have your blender serviced, please contact STARR Life Sciences at: 1-866-978-2779 ext. 5, or technicalsupport@starrlifesciences.com.

3.4. HypoxyDial™ Flow Meter

The flow meter is a type of variable area meter known as a rotameter. It has a tiny ball that floats via drag from the gas as it passes through the barrel. The indicated flow is specified from the vertical center of the ball. Because of the nature of this flow meter, **it is important that the rotameter be oriented vertically in order to allow you to read it accurately. Also, the rotameter is only accurate if the gas pressure at its inlet is 50 psi.**

This particular rotameter is calibrated for oxygen, so if flow measurement accuracy is desired, we provide an expression to allow you to correct for the difference because the HypoxyDial™ can only deliver a maximum of 21% $F_{I_{O_2}}$. It can be shown that the actual flow is related to the flow on the rotameter barrel by the following expression:

$$Q_{actual} = Q_{rotameter} \left(0.875 + 0.125 \frac{F_{I_{O_2}}}{100} \right),$$

where Q_{actual} is the true volume flow rate (L/min),

$Q_{rotameter}$ is the volume flow rate read from the rotameter barrel (L/min) and

$F_{I_{O_2}}$ is the oxygen fraction indicated on the blender dial face (%).

Of course, you can also invert this equation to calculate the rotameter flow that you would set based on a desired actual flow. We have

$$Q_{rotameter} = \frac{Q_{actual}}{\left(0.875 + 0.125 \frac{F_{I_{O_2}}}{100} \right)}.$$

3.5. HypoxyDial™ Humidifier Chamber and Outlet Hose

The HypoxyDial™ System comes equipped with 2 types of outlet connections. The first is a high-pressure oxygen hose that connects directly from the flow meter to a device that has an O_2 DISS connector and **that permits pressures up to 50 psi**, such as an isoflurane dispenser. This hose and any device that it can connect to that has the appropriate DISS fitting are rated for this pressure.

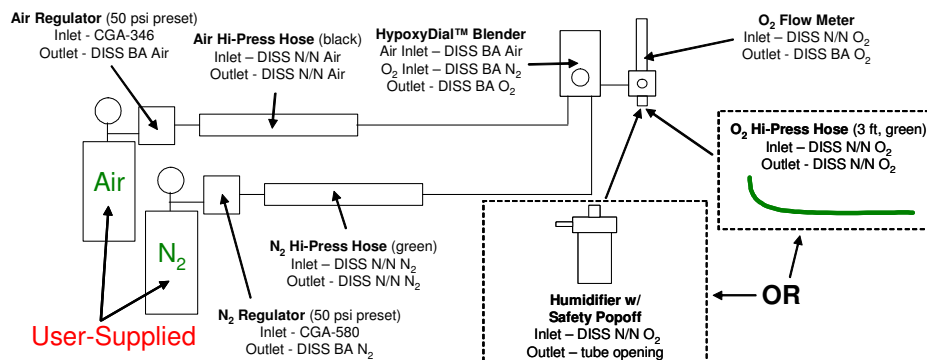
You must assume that other hose connections are NOT rated for this pressure, and you should use caution in connecting this system using such devices. The issue is that if flow passing through whatever is attached to the flow meter is blocked, the pressure inside the attached material will reach 50 psi, causing a potential safety hazard.

To accommodate the use of the HypoxyDial™ with devices not properly rated for pressure, we provide a second connection option – the humidifier chamber, which also connects directly to the outlet of the flow meter. It has a hose barb port that accommodates tubing from 1/8 to 1/4 inch. In addition to allowing you to humidify the gas if you choose, it more importantly has a safety feature to prevent the downstream pressure from becoming excessive. **The humidifier chamber is equipped with a pressure safety popoff**

valve that allows the gas to vent if the pressure exceeds a threshold of 3 psi. Thus, you **MUST** use the humidifier chamber if the system that you are connecting to cannot accommodate the high-pressure outlet hose.

4. Setting Up the HypoxyDial™ System

Instructions for setting up the HypoxyDial™ System are described here. Please refer to this schematic for assembly of the HypoxyDial™ System.



The following definitions are applicable to the schematic:

CGA – Compressed Gas Association – Standard fittings for high-pressure gas tanks. Each gas type has its own designated number.

DISS – Diameter Index Safety System – Standard set of high-pressure gas fittings designed specifically to prevent inadvertent errors in mechanical connections with medical grade gases.

BA – Body Adaptor – The “male” half of a DISS fitting.

N/N – Nut/Nipple – The “female” half of a DISS fitting.

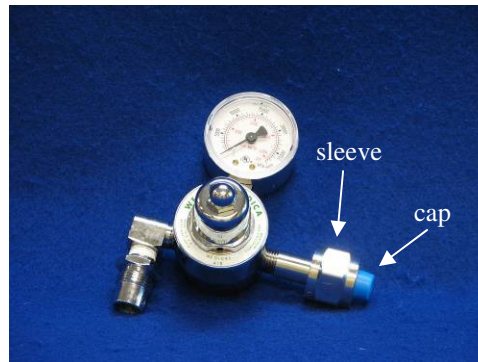
1] Connect the Air and Nitrogen Regulators to the Gas Tanks

The HypoxyDial™ comes with two regulators (air and nitrogen) that are preset to 50 psi. **DO NOT ADJUST** this pressure by turning any knobs on the top of the regulators. The regulators are outfitted with standard Compressed Gas Association (CGA) fittings that will allow them to be connected to their respective tanks. Each regulator should be tightened with a wrench.

To replace any of the gas tanks after the gas has been depleted, you should close the valve on top of the tank, then remove the regulator at the CGA fitting!



Note that the air regulator has a cap on the inlet side. To remove this, simply pull the sleeve toward the regulator body, and it should pop off.



2] Connect the Supply Hoses to the Regulators

The air and nitrogen regulators have special connecting hoses. The air hose is **yellow** and the nitrogen hose is **black**, and the fittings on each are of the DISS type, and therefore cannot be interconnected with each other. Either end of both hoses can be connected to their respective regulators. Simply hand-tighten the end of the hose that fits on the regulator outlet fitting. It is not necessary to use a wrench.



3] Attach the N₂ Hose to the HypoxyDial™ Blender

Lay the blender upside down on a surface, and attach the other end of the nitrogen hose to the appropriate connection on the bottom of the blender. In the correct orientation, the nitrogen inlet will be on the right bottom side of the blender, while the air inlet will be on the left bottom side. Again, the hoses cannot be interchanged.

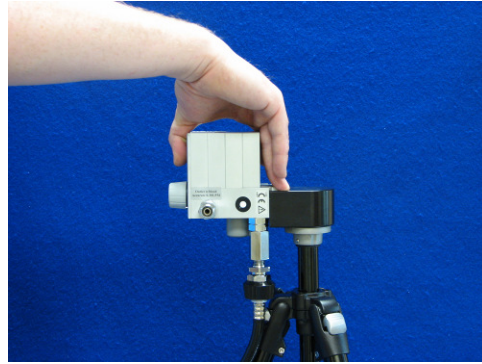


The fitting entering into the blender body is left-handed, so by tightening the hose fitting, you may inadvertently loosen the fitting inside the blender body. To prevent this, you can use a wrench to maintain

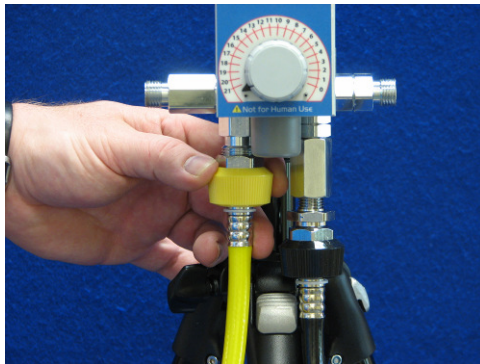
tightness on the body fitting while tightening the hose fitting.

4] Mount the HypoxyDial™ Blender on the Stand

Remove the tripod stand from its box, and retract the legs. Before mounting the blender on the stand, make sure that the bracket on the top of the stand is facing one of the three legs as shown below. This orientation will help to prevent the system from tipping. Next, place the assembled blender in the bracket.



Once the blender is sitting on the stand, attach the other end of the air hose to the fitting on the bottom of the blender.



5] Attach the Flow Meter

Attach the flow meter to either of the outlet ports on the sides of the blender. Be sure to choose the correct port for your application (see “Outlet Delivery Ports” in Section 3.3 above). Once attached, the fitting should be tightened gently with a wrench. **Make sure that the flow meter is in a vertical position so that its reading will be as accurate as possible.**



6a] Attach the High Pressure Outlet Connection (5 ft Hose)

Your HypoxyDial™ comes equipped with 2 different outlet connections. The first outlet connection is a 5 foot (1.5 m) section of high pressure hose that will allow you to connect the HypoxyDial™ directly to an isoflurane dispenser or other device equipped with an oxygen DISS body adaptor, **and that can handle pressures above 50 psi**. This particular hose is equipped with hand-tight nuts, so it is unnecessary to tighten them with a wrench.

This hose can be connected to the flow meter outlet, but you can also opt to connect this high pressure hose directly to the blender without passing through the flow meter, as shown in the figure below. Instructions for attaching the flow meter are provided just above. **Note that if you choose to leave the flow meter in place, and the device to which you are connecting also has a flow meter or other user-adjustable flow-limiting orifice, you should open the flow valve on the HypoxyDial™ flow meter all the way to reduce its flow restriction as much as possible.**



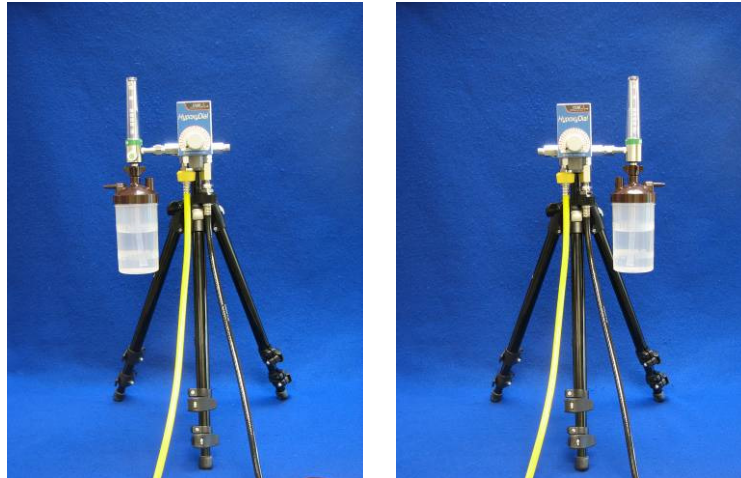
6b] Attach the Low Pressure Outlet Connection (Humidifier Bowl)

The other outlet connection is a humidifier bowl with a pressure safety popoff. This humidifier is a bubble-through type, and it connects directly to the bottom of the flow meter. It has an outlet hose barb that can accommodate tubing between 1/8 and 1/4 inch inner diameter to connect to other devices. The bowl should be filled and operated with the water level between the “minimum” and “maximum” lines. If you do not want to humidify, you can simply use the chamber completely empty.

The most important feature of the humidifier however, is the pressure safety popoff, which vents the system when pressures inside the bowl exceed 3 psi. **Because of its overpressure safety utility, you MUST use the humidifier bowl when connecting the HypoxyDial™ System to devices that are not rated for high pressure!**



Pictures of the fully assembled system are shown below, with the flow meter located on either outlet of the blender.



5. HypoxyDial™ Applications

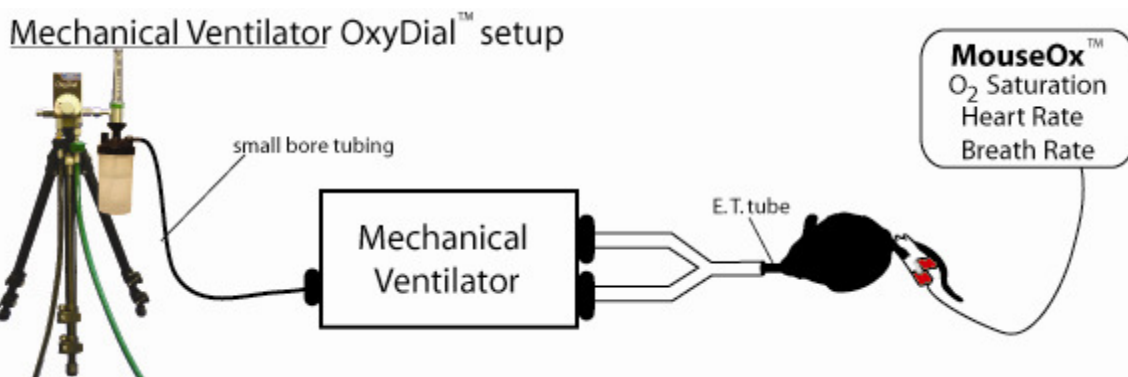
The HypoxyDial™ can be used to conduct hypoxia studies in different applications, which include:

- Provide $F_{I}O_2$ control during mechanical ventilation.
- Provide $F_{I}O_2$ control during isoflurane anesthesia delivery.

Details on how to implement these HypoxyDial™ applications are given in the sections below.

5.1. Mechanical Ventilation Assist

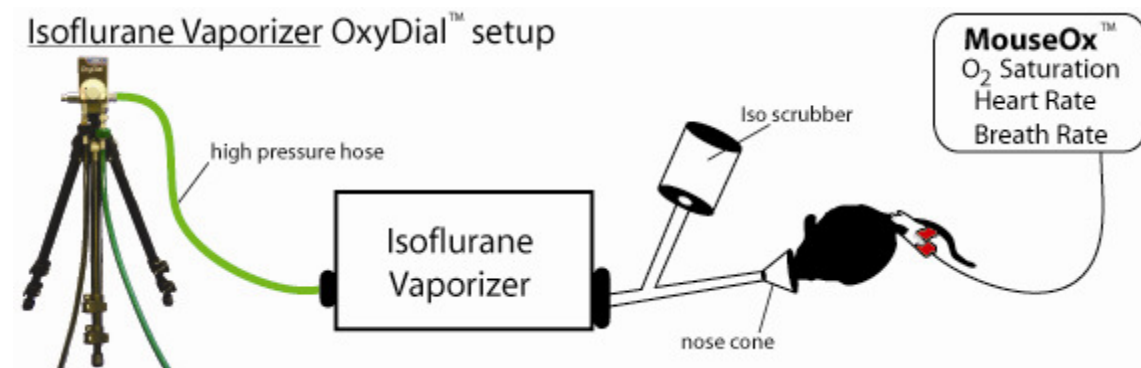
The HypoxyDial™ System can be used to provide hypoxic gas combinations with user-specified oxygen fraction to a mechanical ventilator. A basic functional configuration is shown in the figure below. The HypoxyDial™ should be connected to a location on the ventilator that receives its inlet gas. If the ventilator cannot accommodate the high-pressure outlet hose, you must use tubing in conjunction with the humidifier and pressure safety popoff, as shown in the figure below. If the ventilator requires dry gas, you can simply not fill the humidifier bowl, but you still need to use the humidifier because of its overpressure safety feature.



5.2. Isoflurane Delivery

The HypoxyDial™ can be used to provide gas with a user-specified oxygen fraction to be employed in conjunction with an isoflurane vaporizer. You can simply use the 5 foot high pressure outlet hose to connect to the vaporizer from either the HypoxyDial™ flow meter, or directly from the blender. A typical setup would be similar to that shown in the sketch below.

This system should also be used with a MouseOx® pulse oximeter to allow you to monitor the health of your animals while they are under anesthesia.



6. Warnings, Cautions and Operational Notes

- | | |
|---------|---|
| WARNING | Always use the HypoxyDial™ in an adequately ventilated area. |
| WARNING | DO NOT use the HypoxyDial™ around open flame. |
| WARNING | Place the HypoxyDial™ on a level surface when operating it. |
| WARNING | When mounting the blender on the tripod stand, align blender with one of the legs of the stand to provide more mechanical stability. |
| WARNING | DO NOT lay tubing from the HypoxyDial™ in areas where it can represent a tripping hazard. |
| WARNING | DO NOT lay tubing from the HypoxyDial™ System in areas where it can be inadvertently grabbed such that heavier parts of the system can be tipped or pulled from surfaces. |
| WARNING | If the stand with mounted blender seems like it might tip, extend the legs of the stand further to increase mechanical stability. |
| WARNING | Investigational device only. All parts are NOT for use on humans. |
| WARNING | DO NOT substitute any parts that come with your HypoxyDial™ with other, external parts or fittings. |
| WARNING | Wipe external surfaces of the blender, flow meter and hoses with 10% bleach solution or light detergent in water after each use with animals. |

- | | |
|---------------------|--|
| WARNING | When using low pressure tubing, always use the humidifier chamber with the pressure safety popoff. DO NOT connect low-pressure tubing directly to the flow meter without this safety valve in place. |
| WARNING | The HypoxyDial™ uses high pressure gas. Shut all supply valves and vent gas from the lines before removing or disconnecting any parts from the HypoxyDial™ System. |
| CAUTION | DO NOT obstruct ports or vents on the bottom of the blender. |
| CAUTION | Condensed water in the gas supplies can cause malfunction of this device. Use only clean, dry, medical-grade gases with the HypoxyDial™. |
| CAUTION | Always disconnect the gas sources from the blender when the blender is not in use. |
| OPERATIONAL
NOTE | We recommend that you use an Oxigraf O ₂ -Cap Oxygen Analyzer or equivalent analyzer to verify F _I O ₂ and F _I CO ₂ . |

7. Replacement Parts, Accessories and Technical Support

The following are adjunct or replacement parts for the HypoxyDial™:

HypoxyDial™ Replacement Parts

- #100513 N₂ Regulator
- #100543 Air Regulator
- #100527 N₂ Connection Hose 20ft Black
- #100542 Air Connection Hose 20ft Green
- #100517 Blender Stand
- #100519 Flow Meter
- #100535 High-Pressure Outlet Hose 5ft Green
- #100520 Humidifier

Accessory Devices

- #000001 MouseOx® Control Box
- #000501 OxyDial™
- #000503 HypoxyDial™

STARR Life Sciences® values its customers and is dedicated to providing quality products and solutions to meet your needs. If you have any questions, or you need ANY replacement parts, please call or email STARR Life Sciences at: 1-866-978-2779 ext. 5, or technicalsupport@starrlifesciences.com.

8. Intellectual Property Protecting the HypoxyDial™

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STARR Life Sciences, the STARR Life Sciences logo and other STARR Life Sciences marks are owned by STARR Life Sciences Corporation and may not be used without express written permission of STARR Life Sciences Corporation.

Technology Warning: US and foreign patents are pending. Unauthorized reproduction or distribution of this HypoxyDial™ system, or certain portions of it, will result in civil and criminal penalties, and will be prosecuted to the fullest extent possible under the law.

9. Warranties and Liabilities

Limited Warranty & Disclaimer

STARR Life Sciences® (“SLS”) warrants its non-disposable hardware and sensors (the “Non-disposable Products”) against defects in material, workmanship, and performance for a period of one (1) year from the date of shipment by SLS (the “Warranty Period”). SLS warrants that the Non-disposable Products will meet the electronic and mechanical specifications stated in the SLS user manual, although the specifications are subject to change without notice. SLS, at its option, will repair or replace a Non-disposable Product that is found to be defective during the Warranty Period. Defective Non-disposable Products must be received at STARR Life Sciences Corp., 333 Allegheny Ave., Suite 300, Oakmont, PA 15139 no more than thirteen (13) months from the original date of shipment by SLS. All shipments must include a Return Authorization Number (RMA #), obtainable from SLS, and must be sent freight prepaid by the sender.

This warranty is nontransferable. This warranty does not apply to any defects or damages caused by an animal or resulting from alteration, modification, neglect, misuse, usage of improper power sources, damage in transportation, abuse, or any cause other than normal use of the Non-disposable Products. This warranty does not apply to products resold by SLS that are manufactured by other companies. No warranty or claim is made by SLS, regarding the efficacy of any product for any particular application.

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